phospholipid envelope or a bioadhesive polymer coating, said lipid being characterized as an emulsion of lipid droplets dispersed in an aqueous medium, and said lipid and said biologically active agent being present in a ration of from about 10:1 to about 1:10, such that said biologically active agent is carried bys aid lipid of said lipid carrier and said biologically active agent is thereby released from said lipid in a sustained manner and over a prolonged period of time, such that said lipid carrier has a property of high adhesion to the mucosal tissue; and

B2 cancel

(b) administering the formulation to the mucosal tissue.

REMARKS

Claims 1, 5 and 12-30 are under consideration. Claims 1 and 29 have been amended.

REJECTION UNDER 35 U.S.C. §102(b)

The Action rejects claims 1, 12-18, 25, 26, 28-30 under 35 U.S.C. 102(b) as being anticipated by WO 88/00824 because the action states that WO discloses liposomal formulations for mucosal application which contain egg lecithin and antibiotics. The Action did not find persuasive applicants argument that Patent WO 88/00824 teaches, as an essential element, "positively charged lipid components,"—not present in the present invention, because such a limitation is not included in the claims.

In response, applicants have amended claims 1 and 29 and all claims thereon. Therefore, the above rejection should be withdrawn.

The Action also rejects claims 1, 12-18, 25, 26, 28-30 under 35 U.S.C. 102(b) as being anticipated by Amselem (US Patent No. 5,662,932) because the Action states "Amselem discloses nanoemulsions containing antifungal agent, miconazole, egg

lecithin, tricaprin, cholesterol, oleic acid and tocopherol succinate. The drug:lipid ratios fall within the claimed ratios. The composition further contains surfactants such as Tweens. The modes of administration are oral, rectal and nasal." The Action did not find persuasive applicants argument that Amselem teaches, as an essential element, "a phospholipid envelope,"—not present in the present invention, because such a limitation is not included in the claims.

In response, applicants have amended claims 1 and 29 and all claims thereon. Therefore, the above rejection should be withdrawn.

The Action also rejects claims 1, 5, and 12-30 under 35 U.S.C. 102(e) as being anticipated by Schwartz (US Patent No. 6,117,415). The Action states that Schwartz discloses oil in water emulsions containing either chlorhexidine or triclosan, egg lecithin, triglyceride, alpha-tocopherol hemisuccinate, Tween, peppermint oil, as well as the other claimed surfactants. The particle sizes in Schwartz are 250 nm to 350 nm. The Action did not find persuasive applicants argument that Schwartz, as an essential element, "a bioadhesive polymer coating,"—not present in the present invention, because such a limitation is not included in the claims.

In response, applicants have amended claims 1 and 29 and all claims thereon. Therefore, the above rejection should be withdrawn.

REJECTION UNDER 35 U.S.C. 103(a)

The Action rejects claims 1, 12-18, 25, 26, 28-30 under 35 U.S.C. 103(a) as unpatentable over WO 88/00824 because although WO does not teach the entire claimed range of lipid to active agent, it is obvious to one skilled in the art to vary the

amount of active agents from the amounts in WO since the amounts of active agents to be administered depend on the condition of the disease and other factors.

In response, the applicant disagrees with the Action. "A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." (MPEP 2141.02). Patent WO 88/00824 teaches as an essential element in claim 1, positively charged vesicle forming lipid components, and as stated above, limits the amount of negatively charged lipid components so that the positive charge is not reduced. WO teaches away from the present invention. The present invention teaches, contrary to the reference, the use of amphiphilic phospholipids; the present invention does not require a positively charged lipid component therefore, as a matter of fact and law, the above rejection cannot be upheld. Furthermore, the present invention results in unexpected health benefits because it provides formulations having desirable properties of carrying large amounts of active agents for controlled and prolonged release at a desired site such as mucous membrane surfaces for which the lipid carrier has high adhesive properties. All these factors provide unexpected health benefits for delivery of drugs. Therefore, the above rejection should be withdrawn.

The Action rejects claims 1, 12-20, 22, 24-30 under 35 U.S.C. 103(a) as being unpatentable over Amselem (US Patent No 5, 662, 932) because although Amselem does not teach the entire claimed range of lipid to active agent, it is obvious to one skilled in the art to vary the amount of active agents from the amounts in Amselem since the amounts of active agents to be administered depend on the condition of the disease and other factors

In response, the applicant disagrees with the Action. The claimed invention as a whole would not have been obvious in light of Amselem because the reference teaches a lipid core with a phospholipid envelope as an essential element, but no such envelope is required in the present invention. (MPEP 2141.02). Furthermore, the present invention results in unexpected health benefits because it provides formulations having desirable properties of carrying large amounts of active agents for controlled and prolonged release at a desired site such as mucous membrane surfaces for which the lipid carrier has high adhesive properties. All these factors provide unexpected health benefits for delivery of drugs. Therefore, as a matter of fact and law, the above rejection cannot be upheld.

The Action rejects claims 1, 5, 12-30 under 35 U.S.C. 103(a) as being unpatentable over Schwarz because it would be obvious to one of ordinary skill in the art to vary the active agent amounts from the guidance provided by Schwarz, since the amounts of active agents to be administered depend on the condition of the disease and other factors.

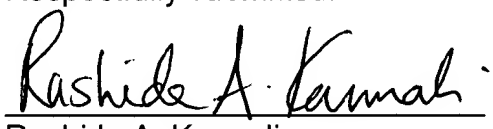
In response, the applicant disagrees with the Action. The claimed invention as a whole would not be obvious in light of Schwartz. Schwarz has as an essential element a bioadhesive polymer coating on lipid particles which is necessary for adherence to mucosal membranes. The lipids of the present invention do not have a bioadhesive coating necessary to adhere to mucosal membranes, so the present invention is not obvious in light of Schwarz.). Furthermore, the present invention results in unexpected health benefits because it provides formulations having desirable properties of carrying large amounts of active agents for controlled and prolonged release at a desired site

such as mucous membrane surfaces for which the lipid carrier has high adhesive properties. All these factors provide unexpected health benefits for delivery of drugs. Therefore, as a matter of fact and law, the above rejection cannot be upheld.

Therefore, claims 1, 5, 12-30 are in condition for allowance and notice to that effect is earnestly solicited. If, for any reason, the Examiner should deem that this application is not in condition for allowance, the Examiner is respectfully requested to telephone the undersigned attorney to resolve any outstanding issues.

Should claim generic claim 1 and claims 5, 12-30 pertaining to the election of the species disinfectants, be granted, then applicants request that claims claims 2-4 and 6-11 be reinstated and allowed as indicated by the Examiner (applicants' attorney discussed the Restriction by telephone with the Examiner), and in accordance with the terms of the Restriction election made by applicants on October 25, 2001.

Respectfully submitted:



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MARKED UP COPY OF CLAIM AMENDMENTS UNDER 37 C.F.R. 1.121

Amend the following claims:

1. A formulation for application to a mucosal tissue selected from the group consisting of nasal, ophthalmic, oral cavity, gastrointestinal, respiratory, vaginal and rectal, the formulation comprising

(a) a biologically active agent selected from the group consisting of antibiotic, antiviral agent, antifungal agent, disinfectant, nutrient, anti-inflammatory agent, local anesthetic and essential oil; and

(b) a lipid carrier, said lipid carrier having no positively charged lipid but instead including at least one lipid selected from the group of amphiphilic phospholipids consisting of yolk lecithin, Soya lecithin, phosphatidylglycerol and phosphatidylcholine, said lipid having no phospholipid envelope or a bioadhesive polymer coating, said lipid being characterized as an emulsion of lipid droplets dispersed in an aqueous medium, and said lipid and said biologically active agent being present in a ration of from about 10:1 to about 1:10, such that said biologically active agent is carried bys aid lipid of said lipid carrier and said biologically active agent is thereby released from said lipid in a sustained manner and over a prolonged period of time, such that said lipid carrier has a property of high adhesion to the mucosal tissue.

29. A method of administering a formulation to a mucosal tissue, wherein said mucosal tissue is selected from the group consisting of nasal, ophthalmic, oral cavity, gastrointestinal, respiratory, vaginal and rectal, comprising the steps of

(a) providing the formulation, the formulation featuring

(i) a biologically active agent selected from the group consisting of antibiotic, antiviral agent, antifungal agent, disinfectant, nutrient, anti-inflammatory agent, local anesthetic and essential oil; and

(ii) a lipid carrier, said lipid carrier having no positively charged lipid but instead including at least one lipid selected from the group of amphiphilic phospholipids consisting of yolk lecithin, Soya lecithin, phosphatidylglycerol and phosphatidylcholine, said lipid having no phospholipid envelope or a bioadhesive polymer coating, said lipid being characterized as an emulsion of lipid droplets dispersed in an aqueous medium, and said lipid and said biologically active agent being present in a ration of from about 10:1 to about 1:10, such that said biologically active agent is carried bys aid lipid of said lipid carrier and said biologically active agent is thereby released from said lipid in a sustained manner and over a prolonged period of time, such that said lipid carrier has a property of high adhesion to the mucosal tissue; and

(b) administering the formulation to the mucosal tissue.